## Food and Drug Administration, HHS

for 48 hours after all signs have subsided. If no response is seen after 3 days of treatment, therapy should be discontinued and diagnosis reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998]

## § 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

- (a) Specifications. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin with clavulanate potassium equivalent to 12.5 milligrams of clavulanic acid.
- (b) *Sponsor*. See No. 000069 ir §510.600(c) of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. 6.25 milligrams (equivalent to 5 milligrams amoxicillin and 1.25 milligrams clavulanic acid) per pound of body weight twice daily.
- (ii) Indications for use. Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due strains susceptible of betalactamase (penicillinase) producing Staphulococcus aureus. nonbetalactamase Staphylococcus aureus, Staphylococcus spp., Streptococcus spp., and Escherichia coli. Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bac-
- (iii) Limitations. Administer for 5 to 7 days or 48 hours after all symptoms subsided. Deep pyoderma may require 21 days, not to exceed 30 days. If no improvement is seen in 5 days, discontinue therapy and reevaluate the case. Not for use in dogs maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (2) Cats—(i) Amount. 62.5 milligrams (1 milliliter) (50 milligrams of amoxicillin and 12.5 milligrams clavulanic acid) twice daily.

- (ii) Indications for use. Treatment of feline skin and soft tissue infections, such as wounds, abscesses and cellulitis/dermatitis due to susceptible strains of beta-lactamase (penicilinase) producing S. aureus, nonbeta-lactamase S. aureus, Staphylococcus spp., Streptococcus spp., E. coli, Pasteurella multocida, and Pasteurella spp.
- (iii) Limitations. Administer 48 hours after all symptoms have subsided. If no improvement is seen after 3 days of treatment, discontinue therapy and reevaluate diagnosis. Maximum duration of treatment should not exceed 30 days. Not for use in cats maintained for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37320, Aug. 18, 1992, as amended at 60 FR 55659, Nov. 2, 1995; 63 FR 13121, Mar. 18, 1998]

## §520.90 Ampicillin oral dosage forms.

## §520.90a Ampicillin capsules.

- (a) *Specifications*. Each capsule contains 125 milligrams or 250 milligrams of ampicillin.
- (b) *Sponsor*. See No. 000008 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. 5 to 10 milligrams per pound of body weight, e.g., one 125 mg capsule per 14 to 25 pounds, given 2 to 4 times daily; for animals weighing 6 to 14 pounds, one capsule twice daily.
- (ii) Indications for use. Treatment of urinary tract infections (cystitis) due to Proteus spp., hemolytic and non-hemolytic streptococci, beta hemolytic streptococci, and Escherichia coli. In upper respiratory tract infections tracheobronchitis (kennel cough), tonsillitis due to alpha and beta hemolytic streptococci, hemolytic positive staphylococci, E. coli, and Proteus spp. In infections associated with abscesses, lacerations, and wounds due to Staphylococcus spp. and Streptococcus spp.
- (iii) Limitations. Bacteriologic studies to determine the causative organisms and their susceptibility to ampicillin should be performed. Use of the drug is contraindicated in animals with a history of an allergic reaction to any of